**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**WASHINGTON, D.C. 20460**

**OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES**

**June 24, 2008**

**MEMORANDUM**

**SUBJECT:** Risk Assessment and Science Support Branch's (RASSB's) Review of a Tolerance Exemption Increase for All ADBAC Actives and Petition (8F7323) to Amend 40 CFR § 180.940 (a) for n-alkyl ($C_{12}$-$C_{14}$) dimethyl ethylbenzyl ammonium chloride.

**FROM:** Sherrie L. Kinard, Chemist, Team 1
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

**THROUGH:** Norm Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510P)

**TO:** Dennis Edwards, Branch Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)

**Chemical**: All ADBAC Actives and n-alkyl ($C_{12-14}$) dimethyl ethylbenzyl ammonium chloride

**PC Code**: 069104, 069105, 069106, 069154, 069184, 128928

**CAS #:** 53516-76-0, 68424-85-1, 8001-54-5, 85409-23-0, 68424-85-1, 63449-41-2

**DP Barcodes**: D350125

## I. INTRODUCTION AND BACKGROUND

### 1. Introduction

A petition has been submitted to the Agency which requests that the 40 CFR § 180.940 (a) be amended to increase the end use solution concentration permitted for the quaternary sanitizer, n-alkyl ($C_{12}$-$C_{14}$) dimethyl ethylbenzyl ammonium chloride. The proposed amendment requests that the tolerance exemption for n-alkyl ($C_{12}$-$C_{14}$) dimethyl ethylbenzyl ammonium chloride be increased from 200 ppm to 400 ppm when it is used as an active ingredient in food-

contact surface sanitizing products. Approval of this petition to increase the tolerance exemption level from 200 ppm to 400 ppm will create consistency with limits previously approved in 40 CFR 180.940(c) for food processing equipment and utensils and would expand the limits to include food contact surfaces in public eating places and dairy processing equipment. The labels being considered for this tolerance exemption increase are currently registered with the Agency (EPA registration numbers 1839-46, 1839-54, 1839-158, and 1839-55) at a use rate of 200 ppm. Supplementary to the review of the proposed tolerance exemption increase, the residential and occupational risks associated with the labeled uses were also evaluated. A proposed RED was completed for the ADBAC quaternary ammonium chloride chemicals for uses in food handling establishments, food processing establishments, and bottling/packaging establishments. Additionally, a similar petition for ADBAC, another quaternary ammonium compound, has been previously reviewed using data that has been collected and reported by the Quats Residue Group (QRG) Joint Venture and Consumer Specialty Products Association (CSPA).

This document also includes a review of a tolerance exemption increase for all ADBAC active ingredients, n-alkyl ($C_{12-18}$) dimethyl benzyl ammonium chloride (PC Codes: 069104, 069105, 069106, 069184, and 128928), currently registered for use on food contact surfaces from 200 ppm to 400 ppm when used as food-contact surface sanitizing products. The previous ADBAC petition review (D340428 and D340759) has been used as surrogate for this review.

## 2. Petition

Technology Sciences Group, Inc., on behalf of Stepan Company has submitted this petition which requests that the Agency amend 40 CFR § 180.940 (a) by increasing the end-use concentration of the quaternary ammonium compound n-alkyl ($C_{12-14}$) dimethyl ethylbenzyl ammonium chloride in the sanitizing solution from 200 to 400 ppm of active ingredient (a.i.). The use sites covered under § 180.940 (a) are: food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils. The Agency is including a review to amend 40 CFR § 180.940 (a) by increasing the tolerance exemption for all ADBAC active ingredients currently registered for use on food contact surfaces from 200 ppm to 400 ppm when used as food-contact surface sanitizing products.

**The 40 CFR § 180.940 (a) should read:**

| Pesticide Chemical | CAS Reg. No. | Limits |
|---|---|---|
| Quaternary Ammonium Compounds n-alkyl ($C_{12-18}$) dimethyl benzyl ammonium chloride | 53516-76-0<br>63449-41-2<br>68424-85-1<br>8001-54-5 | When ready for use, the end-use concentration of the all quaternary chemicals in the solution is not to exceed 400 ppm of active quaternary compound. |
| Quaternary Ammonium Compounds n-alkyl ($C_{12-18}$) dimethyl ethylbenzyl ammonium chloride | 85409-23-0 | When ready for use, the end-use concentration of the all quaternary chemicals in the solution is not to exceed 400 ppm of active quaternary compound. |

**The following listed in the 40 CFR § 180.940 (a) should be deleted:**

| Pesticide Chemical | CAS Reg. No. | Limits |
|---|---|---|
| Quaternary Ammonium Compounds n-alkyl ($C_{12-14}$) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu) 377-384 | None | When ready for use, the end-use concentration of the all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound. |

### 2.1. Reference Label and Chemical Identity

The registrant has submitted a reference product label: **BTC 2125M 20% Solution** (EPA Reg. No. 1839-155), which contains the following product ingredients:

| | |
|---|---|
| Alkyl (60% $C_{14}$, 30% $C_{16}$, 5% $C_{12}$, 5% $C_{18}$) dimethyl benzyl ammonium chloride | 10% a.i. |
| Alkyl (68% $C_{12}$ , 32% $C_{14}$) dimethyl ethylbenzyl ammonium chloride | 10% a.i. |

The alkyl (60% $C_{14}$, 30% $C_{16}$, 5% $C_{12}$, 5% $C_{18}$) dimethyl benzyl ammonium chloride compounds comprise 10% of the formulation and the alkyl (68% $C_{12}$, 32% $C_{14}$) dimethyl ethylbenzyl ammonium chloride comprise 10% of the formulation for a total of 20% active quaternary compounds. The alkyl groups contain 12 to 14 carbon atoms, in or on all foods, when residues are the result of the lawful application of a registered pesticide containing not more than 400 ppm of all active quaternary compounds when used as a sanitizing solution in food handling establishments.

The following ADBAC active ingredients; (1) n-alkyl (60% $C_{14}$, 30% $C_{16}$, 5% $C_{18}$, 5% $C_{12}$) dimethyl benzyl ammonium chloride (PC Code: 069104); (2) n-alkyl (50% $C_{14}$, 40% $C_{12}$, 10% $C_{16}$) dimethyl benzyl ammonium chloride (PC Code: 069105); (3) n-alkyl (50% $C_{12}$, 30% $C_{14}$, 17% $C_{16}$, 3%$C_{18}$) dimethyl benzyl ammonium chloride (PC Code: 069106); (4) n-alkyl (95% $C_{14}$, 3% $C_{12}$, 2% $C_{16}$) dimethyl benzyl ammonium chloride (PC Code: 069184); (5) and, n-alkyl (67% $C_{12}$, 25% $C_{14}$, 7% $C_{16}$, 1%$C_{8}$, 1%$C_{10}$,1%$C_{18}$) dimethyl benzyl ammonium chloride (PC Code: 128928) are currently registered for use on food contact surfaces. The alkyl groups contain 12 to 18 carbons and not more than 1% each of the groups with 8 to 10 carbon atoms, in or on all foods, when residues are the result of the lawful application of a registered pesticide containing not more than 400 ppm of the n-alkyl dimethyl benzyl ammonium chloride and/or ADBAC active ingredients as a sanitizing solution in food handling establishments.

### 2.2. Proposed n-alkyl dimethyl ethylbenzyl ammonium chloride Uses and Rates

The proposed use practice for n-alkyl ($C_{12}$-$C_{14}$) dimethyl ethylbenzyl ammonium chloride, along with another quaternary ammonium compound, alkyl dimethyl benzyl ammonium chloride (ADBAC), are active ingredients in BTC 2125M products. These products are used in disinfectant, deodorizer, and sanitizer formulations for hospitals, nursing homes, public institutions and industry. They are also used as algaecides in swimming pools and industrial water treatment applications. For sanitizing food contact surfaces, the maximum application rate is currently 0.5 ounces in 4 gallons of water which results in the diluted solution concentrations of 200 ppm total a.i.; however, pending approval of this petition, the maximum application rate for food contact surfaces will be 1 ounce to 4 gallons of water resulting in diluted solution concentrations up to 400 ppm total a.i..

## II. RASSB COMMENTS AND CONCLUSIONS[1]

RASSB has performed an evaluation of n-alkyl dimethyl ethylbenzyl ammonium chloride at the proposed increase in residues from 200 ppm total a.i. to 400 ppm total a.i. which is not covered by existing tolerance exemptions under 40 CFR § 180.940 (a).

The proposed petition results in an increase in potential n-alkyl dimethyl ethylbenzyl ammonium chloride residues in food-contact settings. The petition proposes an increase to the tolerance exemption level from 200 ppm to 400 ppm and also an increase in the maximum application rate to 200 to 400 ppm.

It is noted that the rate of 200 ppm a.i. has been previously evaluated for food-contact settings. RASSB has completed the following evaluation of the proposed n-alkyl dimethyl ethylbenzyl ammonium chloride petition using the previously reviewed ADBAC petition with surface residues resulting from an application of 0.0033 lbs a.i./gal (400 ppm *a.i*).

This document also includes a review for a tolerance exemption increase for all ADBAC active ingredients, n-alkyl ($C_{12\text{-}18}$) dimethyl benzyl ammonium chloride (PC Codes: 069104, 069105, 069106, 069184, and 128928), currently registered for use on food contact surfaces from 200 ppm to 400 ppm when used as food-contact surface sanitizing products. The findings are as follows:

Dietary: No risks of concern resulting from an increase in potential residues in food-contact settings.

1 Note: for a full discussion of toxicology, exposure, etc. the reader should consult with the RED science chapters available in the Public Docket for ADBAC under EPA-HQ-OPP-2006-0339.

Drinking Water: A drinking water assessment was not performed; however, the drinking water assessment that was performed in the ADBAC RED was used as surrogate to aggregate risks from these proposed uses with those currently allowed on other labels containing quaternary ammonium compounds. The drinking water assessment demonstrated no risks of concern.

Residential: No risks of concern resulting from an increase in potential residues in food-contact settings.

Aggregate: No risks of concern resulting from an increase in potential residues in food-contact settings.

Occupational: No risks of concern.

### 1. Toxicology

In assessing the proposed petition, RASSB used appropriate surrogate toxicological end-points for n-alkyl dimethyl ethylbenzyl ammonium chloride, which are taken from the ADBAC RED (see Public Docket under EPA-HQ-OPP-2006-0339):

**Table 1. Summary of Toxicological Endpoints for ADBAC**

| Exposure Scenario | Dose Used in Risk Assessment (mg/kg/day) | Target MOE or UF, Special FQPA SF for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute Dietary (general population; females 13+) | An acute dietary endpoint was not identified in the data base. This risk assessment is not required. | | |
| Chronic Dietary | NOAEL =44 mg/kg/day | FQPA SF = 1<br>UF = 100 (10x inter-species extrapolation, 10x intra-species variation) | Chronic toxicity/carcinogenicity –rat<br>MRID 41947501<br><br>LOAEL = 88 mg/kg/day, based on decreased body weight and weight gain |
| | | **Chronic RfD =** 0.44 mg/kg/day | |
| Incidental Oral (Short-term) | NOAEL = 10 mg/kg/day | FQPA SF = 1<br>UF = 100 (10x inter-species extrapolation, 10x intra-species variation) | Developmental Toxicity – Rat,<br>MRID 42351501<br><br>LOAEL = 30 mg/kg/day, based on decreased body weight and food consumption |
| Incidental Oral (Intermediate-term) | NOAEL = 10 mg/kg/day | FQPA SF = 1<br>UF = 100 (10x inter-species extrapolation, 10x intra-species variation) | Developmental Toxicity – Rat,<br>MRID 42351501<br><br>LOAEL = 30 mg/kg/day, based on decreased body weight and food consumption |

| Table 1. Summary of Toxicological Endpoints for ADBAC | | | |
|---|---|---|---|
| Exposure Scenario | Dose Used in Risk Assessment (mg/kg/day) | Target MOE or UF, Special FQPA SF for Risk Assessment | Study and Toxicological Effects |
| Short-term Dermal | NOAEL= 20 mg a.i./kg/day<br><br>(333 µg/cm$^2$)a | FQPA SF = 1<br>UF = 10 (3x inter-species extrapolation, 3x intra-species variation) | 21-day dermal toxicity- guinea pigs MRID 41105801<br><br>LOAEL = 40 mg a.i./kg/day, based on denuded non-vascularized epidermal layer |
| Short-term dermal | NOAEL = 20 mg ai/kg/day<br><br>(80 µg ai/cm$^2$) b | UF = 10 (3x inter-species extrapolation, 3x intra-species variation) | 21-day dermal toxicity in rats MRID 41499601<br><br>20 mg ai/kg/day is the highest dose tested before irritation became significant at day 43. |
| Short-term Dermal (technical grade a.i.) | No endpoint identified from the available data on dermal irritation. Dermal irritation in the 90-day dermal toxicity study was not evident until day 43 (MRID 41499601). | | |
| Long-term Dermal (TGAI) | No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical grade that could be tested without irritation effects. | | |
| Inhalation[c] (Any time point) | NOAEL= 3 mg/kg/day<br>MOE = 100[c] | UF = 100 (10x inter-species extrapolation, 10x intra-species variation)<br><br>Note: an additional 10x is used for route extrapolation to determine if a confirmatory study is needed | Developmental Toxicity – rabbit, MRID 42392801<br><br>LOAEL = 9 mg/kg/day, based on clinical signs of toxicity in maternal rabbits |

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.

a Formulated-based dermal endpoint = (20 mg a.i./kg guinea pig x 0.43 kg guinea pig x 1000 ug/mg) / 25.8cm$^2$ area of guinea pig dosed = 333 µg ai/cm$^2$ .

b TGAI-based dermal endpoint = (20 mg ai/kg rat x 0.2 kg rat x 1000 ug/mg) / 50cm$^2$ area of rat dosed = 80 µg ai/cm$^2$ .

c[a]An additional uncertainty factor of 10x is applied for use of an oral endpoint for route-to-route extrapolation to determine if a confirmatory inhalation toxicity study is warranted.

### 2. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources

allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

## 3. Dietary Assessment

In the absence of data for residues of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC on treated food contact surfaces, the Agency estimated residue levels that may occur in food from the application rates on food contact surfaces. In addition, the food processing and dairy equipment uses of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients have also been addressed.

### 3.1. Utensils

To calculate the Estimated Daily Intake (EDI) for dietary exposures resulting from sanitizing utensils, a number of assumptions were made based on the FDA guidelines (FDA, 2003).

1. When a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). The FDA recommended worst-case concentration for this quantity is 1 mg of solution per square centimeter of treated surface area. In the absence of any other data, this value has been used.

2. The FDA suggests that, as a worst-case scenario, all food that an individual consumes will come into contact with 4,000 $cm^2$ of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility.

3. The value for the amount of active material present on food contact surfaces that is expected to migrate to is based on the standard assumption of 100%. This is a conservative estimate assumes that 100% of the residues available on the surface will be transferred to the food and subsequently ingested.

4. The body weights used for this assessment are: adult man = 70 kg; adult woman = 60 kg, and an infant = 10 kg (USEPA, 1997).

The above assumptions and the following equations were used to calculate EDI and Dietary Daily Dose (DDD):

$$EDI\ (mg/p/day) = AR \times RS \times SA \times F \times 10^{-6} \quad (1)$$

$$DDD\ (mg/kg/day) = EDI/BW \quad (2)$$

| Table 2: Input Parameters for Utensil Sanitization | | |
|---|---|---|
| **Parameter** | **Value** | **Rationale** |
| Residual Solution on Surface (RS) | 1 mg/cm$^2$ | FDA worst-case assumption |
| Area of Treated Surface (SA) | 4,000 cm$^2$ | 100% FDA worst case assumption |
| N-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC concentration in diluted Solution (AR) | 400 ppm | Diluted Solution concentration, based on maximum concentration of BTC 2125M in solution and on maximum concentration of ADBAC. |
| Fraction Transferred(F) | 100% | Standard Assumption |
| Body Weight (kg) (BW)<br>Adult man =<br>Adult woman =<br>Child = | <br>70<br>60<br>10 | EPA, 1997 |

The calculated dietary risks resulting from utensil contact are provided below. These risks are not of concern since the % PAD values are less than 100%.

| Table 3: Calculated EDIs and PADs for Chronic Indirect Dietary Exposures from Utensils | | | |
|---|---|---|---|
| **Population** | **Utensils** | | |
| | **EDI (mg/p/d)[a]** | **DDD (mg/kg/d)[b]** | **% cPAD[c]** |
| Adult males | 1.60 | 0.023 | 5.2 |
| Adult females | | 0.027 | 6.1 |
| Children | | 0.16 | 36.4 |

a. EDI (mg/p/day) = AR x RS x SA x F x $10^{-6}$
b. DDD (mg/kg/day) = EDI (mg/p/day) / BW (kg)
c. % PAD = exposure (DDD) /(cPAD, 0.44 mg/kg/day) x 100.

### 3.2. Countertops

To calculate the Estimated Daily Intake (EDI) from treated countertops, the Indirect Dietary Residue Exposure Model (IDREAM) (Exponent 2006) along with the new residue data that has been submitted by QRG and CSPA were utilized. There are currently two levels of refinement for assessing dietary exposure to antimicrobial pesticide products on countertops and for purposes of this assessment; a Tier 2 approach was used.

A Tier 1 assessment is a two-dimensional approach using default assumptions based on AD's current standard operating procedures (SOP), which are considered to be conservative. These assessments assume 1 mg/cm$^2$ of product residue on countertops and that 100% of the residues are transferred from the 2000 cm$^2$ of countertop into the food consumed by each individual daily. A Tier 1 estimate would be made as follows:

$$1 \text{ mg/ cm}^2 \times 1000 \text{ ppm active concentration} = 0.001 \text{ mg a.i./ cm}^2$$

$$0.001 \text{ mg a.i./ cm}^2 \times (2000) \times 100\% \div (15 \text{ or } 60 \text{ or } 70 \text{ kg bw}) = \text{exposure in mg/kg/d}$$

A Tier 2 assessment is a three-dimensional approach which is still conservative, yet provides a refined exposure estimate compared to that from a Tier 1. For Tier 2 assessment, potential residues are estimated in foods that are prepared on treated countertops. Tier 2 uses food consumption and preparation patterns as well as data and assumptions that are not chemical specific. Foods ingredients are separated into nine categories based on food preparation, food physical properties, and the potential, or likelihood of contact with treated countertops. The nine categories are liquids, fruit, bread, cheese, vegetable, meat, purees (e.g., pudding, oatmeal), pieces (foods normally consumed in small pieces), and powders (foods normally used in powder/granular forms). Assumed countertop residues are converted to estimated residues contacting the countertops using a translation factor for each food category, and default residue transfer efficiency for a representative food. Therefore, IDREAM™ combines estimated countertop residues for surface treatment products, CSFII consumption data, food-specific conversion factors that relate the surface area contacting a countertop to the corresponding weight of the food item, and the transfer efficiency of residues from countertops to food. Conservative assumptions for these analyses include: all disinfectants registered uses to clean kitchen countertops and subsequently prepare foods on those countertops; all foods prepared contact the treated countertop with maximum active ingredient residues and that residues do not diminish over time; there is a 100% likelihood of contact to account for both commercial and residential scenarios; all commercial and households use the same disinfectant product; all foods are prepared and consumed; all foods are prepared on the countertops, and no reduction of residues in food result from cooking or other preparation processes. Tier 2 estimates are calculated as follows:

$$\text{Ingestion (mg/kg/d)} = \text{CSR (mg/ cm}^2\text{)} \times [\text{CSA (cm}^2\text{)} \div \text{FW (g)}] \times \text{LC (\%)} \times \text{RT (\%)} \times \text{ConR (g/kg bw/d)}$$

Where:

| | |
|---|---|
| CSR: | Countertop surface residue (mg/ $cm^2$) |
| CSA: | Contact Surface area from CSFII ($cm^2$) |
| FW: | Weight of a piece/serving of food from CSFII (g) |
| LC: | Likelihood of contact (%) |
| RTE: | Residue transfer efficiency (%) |
| ConR: | Consumption rate of food from CSFII (g/kg bw/d) |

The amounts of residue transferred to food are dependent on food types. This parameter was modified in IDREAM™ such to incorporate the new data that has been generated and submitted by QRG and CSPA. The residue values provided by these constituents were generated by collecting data on the residual levels of ADBAC found on three food types: apple, bread, and bologna. The value for the amount of active material present on food contact surfaces that is expected to migrate to is based on the information that is provided in MRID #468707-03. Study to Demonstrate Transferability Equivalence Amoung Quats and Measure Food Surrogate Transfer Efficiency. Three food types were sampled in this study; bologna, apple, and bread, with bologna yielding the highest average percent transfer rate. The residue data from QRG and CSPA are reported in Table 4.

The detailed IDREAM output tables are provided in Appendix A. All of the calculated indirect dietary exposures are not of a concern.

| Table 4. Food categories and QRG data utilized with IDREAM parameters | | |
|---|---|---|
| **Food Category as Identified in IDREAM™** | **QRG[a] food equivalence** | **Residue Transfer Efficiency** (%) |
| Liquid | NA | 100 |
| Fruit | Apple | 39 |
| Bread | Bread | 0.86 |
| Cheese | Bologna | 47 |
| Vegetable | Apple | 39 |
| Meat | Bologna | 47 |
| Purees | Apple | 39 |
| Pieces | Bread | 0.86 |
| Powders | Bread | 0.86 |

| Table 5: Calculated DDDs and PADs for Chronic Indirect Dietary Exposures | | |
|---|---|---|
| **Exposure Group** | **Countertops** | |
| | **DDD (mg/kg/d)** | **% cPAD[a]** |
| Adult males (13+) | 0.00059 | 0.13 |
| Adult females (13-49) | 0.00055 | 0.12 |
| Children (1-2) | 0.0019 | 0.43 |

a. DDD (mg/kg/day) was provided from the IDREAM model
b. % PAD = exposure (DDD) /(cPAD, 0.44 mg/kg/day) x 100.

### 3.3. Food Processing/Dairy Equipment

N-alkyl dimethyl ethylbenzyl ammonium chloride as well as many ADBAC active ingredients may also be used as a sanitizers or disinfectants for food processing and dairy equipment. The sanitization of food processing and dairy equipment permits product contact with the interior of equipment. FDA utilizes the milk truck model (described in the FDA document, "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions", pages 9-10) (FDA 2003) for these types of uses and this was performed in order to estimate residues that could transfer from treated surfaces to food such as milk. The risks calculated for these uses are not of a concern.

This guidance states on page 9, "For applications limited to use of the food sanitizer on food processing equipment and utensils, the Agency has determined that estimates of sanitary exposure from use in dairy processing plants significantly exceed estimates based on other uses with food processing equipment and utensils. Depending on the available safety data, the petitioner may either submit a petition for the broader use of its sanitizer on 'food processing equipment and utensils including dairy processing plants' or for the more limited use on 'food processing equipment and utensils excepting use in dairy processing plants.'"

Although in practice, consideration of all of the components of a milk handling system should be included as sources of sanitizer residue in milk, for purposes of this assessment, the Agency assumes the sanitized tank truck which transports the milk is the primary source of

residue. It is conservatively assumed that the milk undergoes no additional dilution prior to reaching the consumer. The calculation of the estimated daily intake (EDI) of residual sanitizer solution in milk from use in a dairy processing plant utilized the following equation and assumptions:

EDI = SA x CT x R x AR x CF1 x CF2 x CF3

EDI: Estimated Daily Intake (µg /L milk)
SA: Internal surface area of 413 $ft^2$ is calculated for the tank (413 $ft^2$/truck).
CT: Assuming a cylindrical model for the tank truck, it is assumed to have a 4,000 gal capacity (1 truck/4,000 gallons).
R: When a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface. The FDA recommended worst-case concentration for this quantity is 1 mg of solution per square centimeter of treated surface area. In the absence of data, this value has been used.
AR: Application rate based on label direction, which contains 20% quaternary compounds (or 400 ppm)
CF1: Conversion factor (929 $cm^2$/1 $ft^2$)
CF2: Conversion factor (0.264 gal/1L)
CF3: Conversion factor (1000ug = 1mg)

**Table 3. Estimated Dietary Consumption of Adults and Children from the use of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC a.i. in Dairy Processing Plants**

| Exposure Scenario | Application Rate (% a.i.) | Estimated Daily Intake (µg /L milk) [a] | Adult dietary consumption (µg/day)[b] | Child dietary consumption (µg/day)[c] | Total Dietary Dose (mg/kg/day)[d] | % cPAD (mg/kg/day)[e] |
|---|---|---|---|---|---|---|
| Food processing equipment | 0.004 | 1.13 | 0.15 | 0.38 | Male: $2.1 \times 10^{-6}$ | $4.8 \times 10^{-4}$ |
| | | | | | Female: $2.5 \times 10^{-6}$ | $5.7 \times 10^{-4}$ |
| | | | | | Child: $3.8 \times 10^{-5}$ | $9.0 \times 10^{-3}$ |

a Estimated Daily Intake (ug/L milk) = 413$ft^2$/ truck x 1truck/4000gal x 1mg/$cm^2$ x (0.004%) x 929$cm^2$/$ft^2$ x 0.264gal/1L x 1,000µg/1mg = 1.13µg /L milk ~ 1.13 ppb.
b If an adult (male or female) were to consume 125g of food per day, assumed to be containing 1.13 µg/L of n-alkyl dimethyl ethylbenzyl ammonium chloride, utilizing the following equation: 125g/day x kg/1000g x 1.13µg/L x L/0.96kg, then the person would ingest 0.15µg of n-alkyl dimethyl ethylbenzyl ammonium chloride/ADBAC a.i. per day.
c If an child were to consume 320g of food per day, assumed to be containing 1.13µg/L of n-alkyl dimethyl ethylbenzyl ammonium chloride/ADBAC a.i., utilizing the following equation: 320g/day x kg/1000g x 1.13µg/L x L/0.96kg, then the child would ingest 0.38µg of n-alkyl dimethyl ethylbenzyl ammonium chloride/ADBAC a.i. per day.
d Dietary exposure (mg/kg/day) = Dietary Consumption (mg/day) / Body weight (Where male body weight is 70 kg, female is 60 kg and children is 10 kg and a conversion factor of 1,000ug = 1mg is applied).
e % PAD (population adjusted dose) = exposure (total dietary dose)/ PAD) x 100. The PAD is assumed to be equivalent to the chronic dietary RfD value of 0.44mg/kg/day.

### 3.4. Combined Dietary Exposures and Risks

Combined exposures were calculated for the use of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients in food handling establishments, and risks were not of concern. N-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredient treatments of food processing equipment and dairy equipment are considered to be negligible and were not included in the combined dietary assessment. Therefore, the combined dietary assessment includes utensils and countertop dietary exposures only. The combined dietary exposures from indirect food exposure are not of concern.

**Table 9: Cumulative DDDs and PADs for Chronic Indirect Dietary Exposures**

| Exposure Group | Countertops and Utensils | |
|---|---|---|
| | DDD (mg/kg/d) | % cPAD[a] |
| Adult males (13+) | 0.024 | 5.4 |
| Adult females (13-69) | 0.028 | 6.4 |
| Children (1-2) | 0.16 | 36.4 |

a. Aggregate DDD = Utensil DDD + Countertop DDD
b. % PAD = exposure (DDD) /(cPAD, 0.44 mg/kg/day) x 100.

### 3.5. Drinking Water Assessment

A drinking water assessment is not warranted based on the uses proposed on this label. The indoor hard surface applications are anticipated to result in minimal, if any, runoff of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients into the groundwater. However, n-alkyl dimethyl ethylbenzyl ammonium chloride as well as ADBAC active ingredients are also registered for a variety of residential, institutional, and farm uses. Therefore, for the purposes of this assessment, drinking water estimates from the ADBAC RED were used as surrogates and incorporated into the aggregate dietary assessment. Details of these assessments may be found in the ADBAC RED (see Public Docket under EPA-HQ-OPP-2006-0339).

An acute oral toxicological endpoint was not established. Therefore, only the chronic drinking water exposure was calculated. The adult chronic drinking water dose is 0.009 mg/kg/day (i.e., average EDWC 331 ug/L x 2 L/day consumption x 1/70 kg BW). The children chronic drinking water dose is 0.022 mg/kg/day (i.e., average EDWC 331 ug/L x 1 L/day consumption x 1/15 kg BW). There are no drinking water concerns with n-alkyl dimethyl ethylbenzyl ammonium chloride or ADBAC active ingredients as the concentrations are much lower than the level of concern.

| Table 10. Tier I Estimated Drinking Water Concentrations (EDWCs) Based on Aerial Application of ADBAC on Nursery Ornamentals | | |
|---|---|---|
| Drinking Water Source (Model) | Use rate (lbs ai/A/year) | EDWC (ppb) |
| Surface water (FIRST)<br>Acute (peak)<br>Chronic (annual average) | 906 | <br>13,129<br>331 |
| Groundwater (SCIGROW) | 906 | 5.4 |

### 4. Residential Exposure/Risk Pathway

There are no residential uses associated with this petition; however, since the request is for an increase in the tolerance exemption, certain residential uses were assessed. The exposure scenarios assessed in this document for the representative antimicrobial uses selected by the Agency to represent the residential risks include:

- Indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays).

Exposure Data and Assumptions for Indoor Hard Surfaces

The residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were taken from the PHED data presented in HED's Residential SOPs (USEPA, 1997) and from the CMA data from the EPA memorandum Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (USEPA, 1999). Specific surrogate data used in determining the dermal and inhalation exposures are reported below:

- For the mopping and wiping, the CMA data were used; and
- For trigger pump scenarios the PHED data were used.

The quantities handled/treated for the handler scenarios were estimated based on information from various sources, including Antimicrobial Division estimates.

- For ***mopping*** scenarios, it is assumed that 1 gallon of diluted solution is used.
- For ***wiping and trigger pump spray*** scenarios, it is assumed that 0.5 liter (0.13 gal) of diluted solution is used.

As with the antimicrobial use, homeowners are assumed to complete elements of an application (mix/load/apply) without the use of personal protective equipment.

Post-application scenarios have been developed that encompass multiple products, but still represent a high end exposure scenario for all products represented. Representative post-application scenarios assessed include crawling on treated hard surfaces. Data sources and

methodologies include the HED Residential SOPs (USEPA 2000, 2001), Human and Environmental Risk Assessment (HERA) Guidance Document (2003 and 2005), Pesticide Handlers Exposure Database (PHED), and Outdoor Residential Exposure Task Force (ORETF) studies.

Since no toxicological endpoint of concern was identified for dermal systemic adverse effects, both the handler and the post-application dermal risks were assessed using the short-term toxicological endpoint for dermal irritation. The duration of exposure for most homeowner handler exposures is believed to be best represented by the short-term duration (1 to 30 days). The reason that short-term duration was chosen to be assessed is because the different handler and post-application scenarios are assumed to be episodic, not daily.

### 4.1. Risk Characterization of Antimicrobial Uses

A summary of the residential handler inhalation risks are presented in Table 11. Although the inhalation endpoint represents short, intermediate, and long-term durations, the exposure duration of most homeowner applications of cleaning products is believed to be best represented by the short-term duration. The inhalation toxicological endpoint is based on an oral study because a route-specific inhalation study is not available. The calculated inhalation MOEs are above the target MOE of 100. The dermal MOEs are presented in Table 12. The dermal MOEs are above the target MOE of 10.

**Table 11. Short-term Residential Handler Inhalation Exposures and MOEs**

| Exposure Scenario Application Method | Application Method | Application Rate[a] | Quantity Handled/ Treated per day[b] | Unit Exposure (mg/lb ai)[c] | MOE [d] (Target MOE = 100) |
|---|---|---|---|---|---|
| Application to indoor hard surfaces | Mopping | 0.0033 lb ai/gal | 1 gallon | 2.38 | 23,000 |
| | Wiping | 0.0033 lb ai/gal | 0.13 gallon | 67.3 | 6,200 |
| | Trigger Spray | 0.0033 lb ai/gal | 0.13 gallon | 2.4 | 170,000 |

a Application rates used for mopping, wiping, and trigger spray are the equal to the proposed application rate of 400 ppm of n-alkyl dimethyl ethylbenzyl ammonium chloride.
b Amount handled per day values are AD standards.
c Unit Exposure (mg/lb ai) = Unit Exposure from PHED or CMA (mg/lb ai).
d MOE = NOAEL / Absorbed Daily Dose. [Where short-term NOAEL = 3 mg/kg/day for inhalation]. Target MOE = 100.

| Table 12. N-alkyl dimethyl ethylbenzyl ammonium chloride/ADBAC a.i. Short-term Residential Handler Dermal Risks | | | | | | |
|---|---|---|---|---|---|---|
| Exposure Scenario | Application Method | Application Rate[a] | Quantity Handled/ Treated per day[b] | Hand Unit Exposure Adjusted for Surface Area (mg/lb ai/cm$^2$)[c] | Dermal Skin Irritation Exposure [d] (µg/cm$^2$) | MOE [e] (Target MOE = 10) |
| Application to indoor hard surfaces | Mopping | 0.0033 lb ai/gal | 1 gallon | 0.063 | 0.208 | 1,600 |
| | Wiping | 0.0033 lb ai/gal | 0.13 gallon | 1.341 | 0.575 | 580 |
| | Trigger Spray | 0.0033 lb ai/gal | 0.13 gallon | 0.129 | 0.055 | 6,100 |

a Application rates used for mopping, wiping, and trigger spray are the equal to the proposed application rate of 400 ppm of n-alkyl dimethyl ethylbenzyl ammonium chloride. For all other methods, application rates are the maximum application rates determined from EPA registered labels for n-alkyl dimethyl ethylbenzyl ammonium chloride.

b Amount handled per day values are estimates or label instructions.

c Unit Exposure (mg/lb ai/cm$^2$) = Unit Exposure from PHED or CMA (mg/lb ai) / surface area of hand (820 cm$^2$).

d Dermal Skin Irritation Exposure (µg /lb ai/cm$^2$) = Unit Exposure (mg/lb ai/cm$^2$) x Application Rate (lb ai/gal) x Quantity Treated (gal/day) x 1,000 :µg/mg

e MOE = NOAEL (µg /cm$^2$)/ Surface Residue on Skin (µg/cm$^2$). [Where short-term dermal formulated-based NOAEL = 333 µg/cm$^2$]. Target MOE = 10.

A summary of the residential post application risks are presented in Table 13. Although the inhalation endpoint represents short, intermediate, and long-term durations, the exposure duration of most homeowner applications of cleaning products is believed to be best represented by the short-term duration. The inhalation toxicological endpoint is based on an oral study because a route-specific inhalation study is not available. The calculated dermal and incidental oral MOEs are above the target MOE of 10 and 100, respectively. The inhalation MOEs are above the target MOE of 100 for both scenarios.

| Table 13. Short-term Residential Post Application Risks for Children. | | | |
|---|---|---|---|
| Exposure Scenario | Dermal MOE | Incidental Ingestion MOE | Inhalation MOE |
| Child playing on floor[a] | 1,100 | 610 | NA |
| Child playing on carpet[a] | 1,200 | 330 | NA |

NA = not assessed because negligible exposure is assumed by that route for the exposure for the scenario of concern.

a. These exposures are not resulting from the proposed use associated with this petition; however, are included in the aggregate. For details on the assessment for uses resulting in these exposures, please refer to the ADBAC RED.

## 5. Aggregate Assessment

In order for a pesticide registration to continue, it must be shown that the use does not result in "unreasonable adverse effects on the environment". Section 2 (bb) of FIFRA defines this term to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with standard under section 408..." of FFDCA. Consequently, even though no pesticide tolerances have been established for n-alkyl dimethyl ethylbenzyl ammonium chloride or for ADBAC active ingredients, the standards of FQPA must still be met, including "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there

are reliable information." Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Aggregate risk assessment were conducted for short-term (1-30 days), intermediate-term (1-6 months) and chronic (several months to lifetime) exposures. An acute endpoint was not identified, and therefore, an acute aggregate dietary assessment was not necessary.

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at http://www.epa.gov/pesticides/trac/science/aggregate.pdf). Steps for deciding whether to perform aggregate exposure and risk assessments are listed, which include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

### 5.1. Acute and Chronic Aggregate Dietary Risks

An acute toxicological endpoint was not identified. Therefore, an acute aggregate risk assessment was not conducted. The chronic aggregate risk assessment includes dietary and drinking water exposures. Chronic dietary risk estimates from indirect food uses are presented in Section 3.3. Drinking water exposure estimates are presented in Section 3.5. Table 14 presents a summary of these exposures, including the combined dietary exposures (i.e., all indirect food contact exposures), as well as a total dietary aggregate exposure estimate (i.e., drinking water plus indirect dietary exposures). Based on the results of the chronic aggregate assessment, the %cPAD for adults and children are 5.0% and 22.0%, respectively. Therefore, the chronic dietary risks are not of concern (i.e., less then 100 % of cPAD).

| Table 14. N-alkyl dimethyl ethylbenzyl ammonium chloride/ADBAC a.i. Chronic Aggregate Exposures and Risks (cPAD) | | | | | |
|---|---|---|---|---|---|
| Exposure Routes | Chronic Dietary Exposures (mg/kg/day) | | | | |
| | Countertop Dietary Exposures[a] | Utensil Dietary Exposures[a] | Drinking Water Exposures | Aggregate Dietary Exposures[b] | % cPAD[c] (MOE)[c] |
| ***Adults***[d] | | | | | |
| Oral Ingestion | 0.00059 | 0.027 | 0.009 | 0.037 | 8.4 (1,200) |
| ***Children***[e] | | | | | |
| Oral Ingestion | 0.0019 | 0.16 | 0.022 | 0.18 | 40.9 (240) |

a Dietary (countertops and utensil food contact) exposures are presented in Tables 3 and 5.
b Aggregate Dietary Exposures = indirect dietary + drinking water exposures.
c %cPAD (percent chronic population adjusted dose) = (aggregate exposures / cPAD) x 100. Where cPAD = NOAEL 44 mg/kg/day ÷ 100x uncertainty factor = 0.44 mg/kg/day. MOE = NOAEL of 44 mg/kg/day ÷ aggregate dietary exposures mg/kg/day.
d Adult population used is the highest exposed adult population, adult females 13-69 years of age.
e Children population used is the highest exposed children population, children 1-2 years of age.

### 5.2. Short and Intermediate-term Aggregate Exposures and Risks

Short and intermediate-term aggregate exposures and risks were assessed for adults and children that could be exposed to n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC residues from the use of products in non-occupational environments. The short and intermediate-term aggregate risks account for pesticide exposures from the diet, drinking water, and residential uses. The following list summarizes all of the potential sources of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC exposures for adults and children related to the label and increased tolerance exemptions considered for this petition.

Adult n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC exposure sources:

- handling of cleaning products containing n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients as an a.i. during wiping, mopping, and spraying activities;
- and, eating food having n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC residues from indirect food contact.

Child n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC exposure sources:

- post-application exposures to cleaning product residues containing n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC that are used on hard surfaces (e.g, floors);
- and, eating food having n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC residues from indirect food contact.

The use patterns of the products and probability of co-occurrence must be considered when selecting scenarios for incorporation in the aggregate assessment. Table 15 summarizes the scenarios from this petition included in the short and intermediate-term aggregate assessments.

| | Short-term (ST) Aggregate |
|---|---|
| Adults | ▪ chronic dietary (indirect)<br>▪ handling cleaning products (wipe + trigger pump spray) |
| Children | ▪ chronic dietary – (indirect)<br>▪ post-application to cleaning product on carpets (dermal and oral) from the ADBAC RED |

The chronic dietary exposures were used in both the short and intermediate-term aggregate assessment because chronic dietary exposures occur nearly every day (as opposed to acute dietary exposures occurring on a one-time basis). Therefore, short or intermediate-term non-dietary exposures have a high probability to co-occur with the chronic dietary intake.

Since the toxicity endpoints for the oral, dermal, and inhalation routes of exposure are based on different toxic effects, these three routes of exposure are not aggregated together. Instead, the aggregate assessment is based solely on the co-occurrence of the same route of exposures. Aggregate risks were calculated using the total MOE approach outlined in OPP guidance for aggregate risk assessment (August 1, 1999, Updated "Interim Guidance for Incorporating Drinking Water Exposure into Aggregate Risk Assessments"). The aggregate MOE for adults is 2,000 for oral, 480 for dermal with a target MOE of 10, and 2,000 for inhalation with a target MOE of 100. These aggregate MOEs demonstrate risks that are not of concern for adults. For children, the aggregate risk estimate for each of the routes of exposure are above the target MOE of 100 for oral and inhalation, and a target MOE of 10 for dermal (MOE=454 for the oral route, 1,200 for the dermal route, and no co-occurrence for the inhalation route); and thus, are not of concern.

**Table 16. Short and Intermediate-term Aggregate Risk (MOE) Assessment**

| Exposure Routes | Chronic Dietary MOE | Cleaning Product MOEs(Adult Applicators & Children Playing) | | | Route-Specific Aggregate MOE |
|---|---|---|---|---|---|
| ***Adults*** | | | | | |
| Oral Ingestion | 1,200 | NA | | | 1,200 |
| Dermal | NA | 1,600 (mop) | 580 (wipe) | 6,100 (spray) | 480 |
| Inhalation | NA | 27,000 (mop) | 7,300 (wipe) | 200,000 (spray) | 2,000 |
| ***Children*** | | | | | |
| Oral Ingestion | 240 | 330 | | | 140 |
| Dermal (ST only) | NA | 1,200 | | | 1,200 |
| Inhalation | NA | NA | | | NA |

Aggregate MOE = $1/((1/MOE_{same\ route}) + (1/_{MOE\ same\ route}) + etc)$

### 6. Cumulative Exposure and Risk

Another standard of section 408 of the FFDCA which must be considered in making an unreasonable adverse effect determination is that the Agency considers "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC active ingredients, and any other substances. N-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC active ingredients do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC active ingredients to have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

### 7. Occupational Exposure Assessment

Potential occupational handler exposure can occur in food handling premises, dairy processing premises, and in food processing premises.

#### 7.1. Occupational Handler Exposures

N-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredient dermal irritation exposures and risks were not estimated for occupational handler exposures. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for those exposed to end-use products containing concentrations of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients that result in classification of category I, II, or III for skin irritation potential will be: long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of n-alkyl dimethyl ethylbenzyl ammonium chloride and/or ADBAC active ingredients in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

Inhalation exposures and risks were presented based on the oral toxicity endpoint (i.e., route-specific inhalation study not available). The surrogate unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study

(USEPA, 1999: DP Barcode D247642) or from the Pesticide Handler Exposure Database (USEPA, 1998). The specific inhalation unit exposures and quantity of ADBAC handled are provided in the Occupational and Residential Exposure chapter for ADBAC.

The inhalation MOEs were calculated for the short and intermediate-term durations for occupational handlers using the oral endpoint.

Risk Characterization for Antimicroibal Uses

The resulting inhalation exposures and MOEs for the representative occupational handler scenarios are presented in Table 17. The calculated MOEs were above the target MOE of 100 for all scenarios, except those listed below.

**Table 17. Short , Intermediate, and Long-term Inhalation Risks Associated with Occupational Handlers**

| Exposure Scenario | Method of Application | Inhalation Unit Exposure (mg/lb a.i.) | Application Rate [a] | Quantity Handled/ Treated per day | Inhalation Daily Dose (mg/kg/day) [b] | Inhalation MOE[c,d] (Target MOE = 100) |
|---|---|---|---|---|---|---|
| **Food Handling/Storage Establishments Premises And Equipment (Use Site Category II)** | | | | | | |
| Application to indoor hard surfaces (including dishes, utensils, equipment) | Low pressure hand wand | 0.681 | 0.0033 lb ai/gal | 2 gallons | 0.00007 | 40,000 |
| | Mop | 2.38 | 0.0033 lb ai/gal | 2 gallons | 0.0003 | 11,000 |
| | Wipe | 67.3 | 0.0033 lb ai/gal | 0.26 gallons | 0.0010 | 3,100 |
| | Trigger pump sprayer | 1.3 | 0.0033 lb ai/gal | 0.26 gallons | 0.00002 | 160,000 |
| | Immersion, Flooding, Circulation | 1.89 | 0.0033 lb ai/gal | 2 gallons | 0.0002 | 14,000 |

ST = short-term, IT = intermediate-term, LT = long-term, N/A= No data available

a Application rate used is the proposed application rate of 400 ppm of n-alkyl dimethyl ethylbenzyl ammonium chloride.

b Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x absorption factor (1.0 for inhalation) x application rate x quantity treated / Body weight (60 kg for inhalation).

c MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where NOAEL = 3 mg/kg/day for all inhalation exposure durations]. Target MOE = 100.

d The MOEs refer to short-term and intermediate-term duration unless indicated otherwise.

## 7.2. Occupational Post-application Exposures

The occupational post-application dermal and inhalation exposures are assumed to be negligible for the use sites listed under 40 CFR § 180.940 (a). The use sites covered under 40 CFR § 180.940 (a) are: food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils.

## 8. Conclusions

In conclusion, the above represents RASSB's evaluation of the proposed petition for the increased application rate and tolerance exemption from 200 ppm to 400 ppm for n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC active ingredients. There appear to be no dietary, residential, or occupational risks of concern resulting from an increase in the tolerance exemption or from an increase in the end use solution concentration permitted for the quaternary sanitizers, n-alkyl dimethyl ethylbenzyl ammonium chloride and ADBAC active ingredients, to food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils.

If there are questions on the above, please contact RASSB.

# Appendix A

IDREAM Inputs and Results:

| **IDREAM Tier 2 - Incidental Ingestion Exposure** | | |
|---|---|---|
| **Subject active ingredient** | **400 ppm n-alkyl dimethyl ethylbenzyl ammonium chloride** | |
| **Product residue** | **1** | **mg/cm²** |
| **In-use active conc (%)** | **0.040%** | |
| **Active surface residue** | **0.0004** | **mg/cm²** |
| **CHRONIC ASSESSMENT** | | |

| **Subpopulation** | **Tier 2 Chronic Exposure (mg/kg/d)** | **%cPAD** |
|---|---|---|
| Children 1-2 | 0.00189 | 0.429 |
| Children 3-5 | 0.00150 | 0.341 |
| Adults 13+ | 0.00059 | 0.134 |
| Females 13-49 | 0.00055 | 0.125 |

**TIER 2 MODEL - Children aged 1-2** **Active ingredient: 400 ppm n-alkyl dimethyl ethylbenzyl ammonium chloride**

modified to match the first section of the children 1-2 years old and includes the quat residue data for the % residue transfer, as well as 100% likelihood

**CHRONIC EXPOSURE ASSESSMENT**

| Food Category | Contact Surface Area ($cm^2$) | Weight of Serving/ Piece (g) | Likelihood of Contact (%) | Residue Transfer Efficiency (%) | Residue Translation Factor ($cm^2/g$) | Quat Surface Residue ($mg/cm^2$) | Residue in Food (mg/g) | Mean Food Consumption Rate (g/kg bw) | Ingestion Exposure (mg/kg/d) |
|---|---|---|---|---|---|---|---|---|---|
| Liquid | 250 | 240 | 0% | 100% | 0 | 0.0004 | 0 | 70.80 | 0 |
| Solid | | | | | | | | | |
| Fruit | 28 | 97 | 100% | 39% | 0.11 | 0.0004 | 0.000045 | 6.30 | 0.00028 |
| Bread | 94 | 56 | 100% | 0.86% | 0.01 | 0.0004 | 0.000006 | 8.77 | 0.00005 |
| Cheese | 65 | 49 | 100% | 47% | 0.62 | 0.0004 | 0.000249 | 1.05 | 0.00026 |
| Vegetable | 34 | 99 | 100% | 39% | 0.13 | 0.0004 | 0.000054 | 6.39 | 0.00034 |
| Meat | 103 | 138 | 100% | 47% | 0.35 | 0.0004 | 0.000140 | 5.11 | 0.00072 |
| Purees | 46 | 107 | 100% | 39% | 0.17 | 0.0004 | 0.000067 | 3.17 | 0.00021 |
| Pieces | 0.8 | 1.2 | 100% | 0.86% | 0.01 | 0.0004 | 0.000002 | 1.27 | 0.00000 |
| Powders | 123 | 30 | 100% | 0.86% | 0.04 | 0.0004 | 0.000014 | 1.32 | 0.00002 |
| | | | | | | | | **Total Ingestion Exposure:** | 0.00189 |

**TIER 2 MODEL - Children aged 3-5** **Active ingredient: 400 ppm n-alkyl dimethyl ethylbenzyl ammonium chloride**

modified to match the first section of the children 3-5 years old and includes the quat residue data for the % residue transfer, as well as 100% likelihood

**CHRONIC EXPOSURE ASSESSMENT**

| Food Category | Contact Surface Area (cm²) | Weight of Serving/ Piece (g) | Likelihood of Contact (%) | Residue Transfer Efficiency (%) | Residue Translation Factor (cm²/g) | Quat Surface Residue (mg/cm²) | Residue in Food (mg/g) | Mean Food Consumption Rate (g/kg bw) | Ingestion Exposure (mg/kg/d) |
|---|---|---|---|---|---|---|---|---|---|
| Liquid | 250 | 240 | 0% | 100% | 0 | 0.0004 | | 50.07 | 0 |
| Solid | | | | | | | | | |
| Fruit | 28 | 97 | 100% | 39% | 0.113 | 0.0004 | 0.000045 | 3.59 | 0.00016 |
| Bread | 94 | 56 | 100% | 0.86% | 0.014 | 0.0004 | 0.000006 | 4.17 | 0.00002 |
| Cheese | 65 | 49 | 100% | 47% | 0.623 | 0.0004 | 0.000249 | 0.89 | 0.00022 |
| Vegetable | 34 | 99 | 100% | 39% | 0.134 | 0.0004 | 0.000054 | 2.80 | 0.00015 |
| Meat | 103 | 138 | 100% | 47% | 0.351 | 0.0004 | 0.000140 | 4.88 | 0.00068 |
| Purees | 46 | 107 | 100% | 39% | 0.168 | 0.0004 | 0.000067 | 3.19 | 0.00021 |
| Pieces | 0.8 | 1.2 | 100% | 0.86% | 0.006 | 0.0004 | 0.000002 | 9.22 | 0.00002 |
| Powders | 123 | 30 | 100% | 0.86% | 0.035 | 0.0004 | 0.000014 | 1.65 | 0.00002 |
| | | | | | | | | **Total Ingestion Exposure:** | 0.00150 |

**TIER 2 MODEL – Adults aged 13+** **Active ingredient: 400 ppm n-alkyl dimethyl ethylbenzyl ammonium chloride**

modified to match the first section of the adults 13+ years old and includes the quat residue data for the % residue transfer, as well as 100% likelihood

**CHRONIC EXPOSURE ASSESSMENT**

| Food Category | Contact Surface Area | Weight of Serving/ Piece | Likelihood of Contact | Residue Transfer Efficiency | Residue Translation Factor | Quat Surface Residue | Residue in Food | Mean Food Consumption Rate | Ingestion Exposure |
|---|---|---|---|---|---|---|---|---|---|
| | ($cm^2$) | (g) | (%) | (%) | ($cm^2/g$) | ($mg/cm^2$) | (mg/g) | (g/kg bw) | (mg/kg/d) |
| Liquid | 250 | 240 | 0% | 100% | 0 | 0.0004 | 0 | 20.24 | 0 |
| Solid | | | | | | | | | |
| Fruit | 28 | 97 | 100% | 39% | 0.113 | 0.0004 | 0.000045 | 0.94 | 0.00004 |
| Bread | 94 | 56 | 100% | 0.86% | 0.014 | 0.0004 | 0.000006 | 1.40 | 0.00001 |
| Cheese | 65 | 49 | 100% | 47% | 0.623 | 0.0004 | 0.000249 | 0.29 | 0.00007 |
| Vegetable | 34 | 99 | 100% | 39% | 0.134 | 0.0004 | 0.000054 | 1.87 | 0.00010 |
| Meat | 103 | 138 | 100% | 47% | 0.351 | 0.0004 | 0.000140 | 2.10 | 0.00029 |
| Purees | 46 | 107 | 100% | 39% | 0.168 | 0.0004 | 0.000067 | 0.83 | 0.00006 |
| Pieces | 0.8 | 1.2 | 100% | 0.86% | 0.006 | 0.0004 | 0.000002 | 2.72 | 0.00001 |
| Powders | 123 | 30 | 100% | 0.86% | 0.035 | 0.0004 | 0.000014 | 0.64 | 0.00001 |
| | | | | | | | | **Total Ingestion Exposure:** | 0.00059 |

**TIER 2 MODEL – Females aged 13-49** **Active ingredient: 400 ppm n-alkyl dimethyl ethylbenzyl ammonium chloride**

modified to match the first section of the females 13-49 years old and includes the quat residue data for the % residue transfer, as well as 100% likelihood

**CHRONIC EXPOSURE ASSESSMENT**

| Food Category | Contact Surface Area ($cm^2$) | Weight of Serving/ Piece (g) | Likelihood of Contact (%) | Residue Transfer Efficiency (%) | Residue Translation Factor ($cm^2/g$) | Quat Surface Residue ($mg/cm^2$) | Residue in Food (mg/g) | Mean Food Consumption Rate (g/kg bw) | Ingestion Exposure (mg/kg/d) |
|---|---|---|---|---|---|---|---|---|---|
| Liquid | 250 | 240 | 0% | 100% | 0 | 0.0004 | 0 | 19.94 | 0 |
| Solid | | | | | | | | | |
| Fruit | 28 | 97 | 100% | 39% | 0.113 | 0.0004 | 0.000045 | 0.89 | 0.00004 |
| Bread | 94 | 56 | 100% | 0.86% | 0.014 | 0.0004 | 0.000006 | 1.30 | 0.00001 |
| Cheese | 65 | 49 | 100% | 47% | 0.623 | 0.0004 | 0.000249 | 0.30 | 0.00007 |
| Vegetable | 34 | 99 | 100% | 39% | 0.134 | 0.0004 | 0.000054 | 1.72 | 0.00009 |
| Meat | 103 | 138 | 100% | 47% | 0.351 | 0.0004 | 0.000140 | 1.87 | 0.00026 |
| Purees | 46 | 107 | 100% | 39% | 0.168 | 0.0004 | 0.000067 | 0.84 | 0.00006 |
| Pieces | 0.8 | 1.2 | 100% | 0.86% | 0.006 | 0.0004 | 0.000002 | 2.78 | 0.00001 |
| Powders | 123 | 30 | 100% | 0.86% | 0.035 | 0.0004 | 0.000014 | 0.64 | 0.00001 |
| | | | | | | | | **Total Ingestion Exposure:** | 0.00055 |

Sign-off Date : 06/24/08
DP Barcode No. : D350125